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NOTICE OF ALLOWANCE AND FEE(S) DUE

26021

7590

08/14/2008

HOGAN & HARTSON L.L.P. 1999 AVENUE OF THE STARS SUITE 1400 LOS ANGELES, CA 90067

EXAMINER				
OLSON, ERIC				
ART UNIT	PAPER NUMBER			
1623				

DATE MAILED: 08/14/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786.861	02/24/2004	Thomas P. Hedman	89188.0058	3669

10/786,861 02/24/2004 Thomas P. Hedman 89188.0058

TITLE OF INVENTION: NON-TOXIC CROSSLINKING REAGENTS TO RESIST CURVE PROGRESSION IN SCOLIOSIS AND INCREASE DISC PERMEABILITY

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	11/14/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 26021 7590 08/14/2008 Certificate of Mailing or Transmission HOGAN & HARTSON L.L.P. I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. 1999 AVENUE OF THE STARS **SUITE 1400** LOS ANGELES, CA 90067 (Depositor's name (Signature (Date APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 10/786,861 02/24/2004 Thomas P. Hedman 89188.0058 3669 TITLE OF INVENTION: NON-TOXIC CROSSLINKING REAGENTS TO RESIST CURVE PROGRESSION IN SCOLIOSIS AND INCREASE DISC PERMEABILITY APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional YES \$720 \$300 \$0 \$1020 11/14/2008 **EXAMINER** ART UNIT CLASS-SUBCLASS OLSON, ERIC 1623 514-023000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo ■ Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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1999 AVENUE OI	F THE STARS		ART UNIT	PAPER NUMBER
SUITE 1400 LOS ANGELES, O	CA 90067		1623 DATE MAILED: 08/14/200	8

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 874 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 874 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)	
	 10/786,861	HEDMAN, THOMAS P.	
Notice of Allowability	Examiner	Art Unit	
	Eric S. Olson	1623	
The MAILING DATE of this communication appeal all claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R	(OR REMAINS) CLOSED or other appropriate comn IGHTS. This application is and MPEP 1308.	in this application. If not included nunication will be mailed in due course. THIS subject to withdrawal from issue at the initiative	
1. This communication is responsive to <u>Applicant's amendme</u>	nt submitted July 11, 2008	!·	
2. ☑ The allowed claim(s) is/are <u>1-9</u> .			
 3. ☐ Acknowledgment is made of a claim for foreign priority ur a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☐ Copies of the certified copies of the priority do International Bureau (PCT Rule 17.2(a)). 	been received. been received in Applicat	ion No	
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		le a reply complying with the requirements	
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give			
5. CORRECTED DRAWINGS (as "replacement sheets") mus	st be submitted.		
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached			
1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date			
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date			
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t			
 DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT 			
Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ☐ Interview Paper No 7. ☐ Examiner'	nformal Patent Application Summary (PTO-413), ./Mail Date s Amendment/Comment s Statement of Reasons for Allowance	
	'	u Jiang, Ph.D./ atent Examiner, Art Unit 1623	

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Detailed Action

This office action is a response to applicant's amendment submitted July 11, 2008 wherein claims 19-21 and 31-33 are cancelled. This application is a continuation in part of US application 10/230671, now under interference, filed August 29, 2002, which claims benefit of provisional application 60/316287, filed August 31, 2001. This application also claims benefit of provisional application 60/498790, filed August 28, 2003.

Claims 1-9 are pending in this application.

Claims 1-9 as amended are examined on the merits herein.

Priority

The US parent application 10/230671, filed August 29, 2002 and the provisional applications 60/498790, field August 28, 2003, and 60/316287, filed August 31, 2001, upon which priority is claimed fail to provide adequate support under 35 USC 112, first paragraph for the claimed subject matter of instant claims 1-9 and 19-21 of this application because these applications are not seen to disclose any methods of treating scoliotic spines according to instant claims 1-9 or of increasing permeability or cell viability of intervertebral discs according to instant claims 19-21. Thus, the filing date of the instant claims is deemed to be the filing date of the instant application, February 24, 2004.

Reasons for Allowance

Applicant's amendment, submitted July 11, 2008, with respect to the rejection of instant claims 19-21 and 31-33 under 35 USC 103(a) for being obvious over Slivka et al. in view of Sato et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted July 11, 2008, with respect to the rejection of instant claims 19-21 and 31-33 under 35 USC 103(a) for being obvious over Slivka et al. in view of Desrosiers et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Currently, claims 1-9 are pending in this application and have been examined on the merits herein. These claims are seen to be allowable for the reasons given below:

The claimed invention is seen to be adequately described and enabled by the specification. For example, the treatment of scoliotic spines according to the invention is disclosed on pp. 8-9 of the specification. The examples on pp. 20-29 demonstrate that the claimed treatment increases the stiffness and resistance to bending of the affected spine, parameters that would be expected to reduce or treat scoliosis.

Therefore the claimed invention meets the requirements of 35 USC 112.

The claimed invention is also seen to be novel and non-obvious over the prior art. Although certain prior art references such as Slivka et al. are seen to teach a

method comprising injecting a crosslinking agent into an intervertebral disk, The prior art does not disclose a method wherein this treatment is specifically practiced on a scoliotic spine, but rather is directed to treating damaged intervertebral disks, for example slipped or herniated disks. Furthermore, the state of the art for treating scoliosis involves physical reinforcement of the spine such as bracing or spinal fusion. One of ordinary skill in the art would not have considered a method of crosslinking the intervertebral disk to be obviously useful for treating scoliosis. Therefore the claimed invention is seen to be novel and non-obvious over the prior art.

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Accordingly, Applicant's amendment submitted July 11, 2008, is sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

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Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/

Examiner, Art Unit 1623

8/8/2008

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623